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For: *SPECIFICATION OF DIAGNOSTICS AND THERAPY OF EPSTEIN-BARR VIRUS
IN AUTOIMMUNE DISORDERS*

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §1.56, Applicants cite the following publications, which are listed in the enclosed 21 pages of Form PTO-1449. Enclosed are copies of the International Search Reports for International Application Number PCT/US/91/00682 corresponding to U.S.S.N. 07/648,205 and PCT/US93/03484 corresponding to U.S.S.N. 07/867,819.

This application is a Continuation-In-Part of U.S.S.N. 07/160,604, filed on November 30, 1993, which is a Continuation-In-Part of 07/867,819, filed on April 13, 1992 which is a Continuation-In-Part of 07/648,205, which is a Continuation-In-Part of 07/472,947 now abandoned.

It is believed that no fee is required with this submission. However, if an additional fee is required, the Assistant Commissioner is authorized to charge Deposit Account No. 01-2507.

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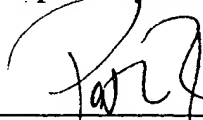
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Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their

claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284


Dated: February 2, 1998

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Applicant: John B. Harley et al.

Serial & Docket No.: 08/781,296

OMRF 161

Filed: January 13, 1997

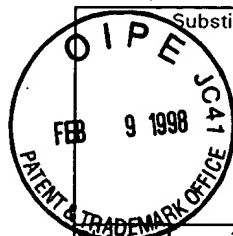
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	08/781,296
Filing Date	January 13, 1997
First Named Inventor	John B. Harley et al.
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	OMRF 161

U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

Examiner's Initials *	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
			O 113 431 A	EP		07/18/84		
			0313 156	EP		04/26/89		
			O 88/09932	PCT		06/03/88		
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OTHER ART -- NON PATENT LITERATURE DOCUMENTS

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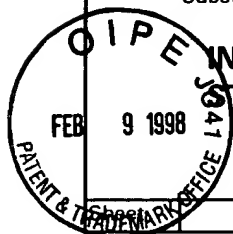
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		Blank, M., et al., "Induction of Systemic Lupus Erythematosus in Naive Mice with T-cell Lines Specific for Human Anti-DNA Antibody SA-1 (16/6 id +) and for Mouse Tuberculosis Antibody TB/68 (16/6 id +) <u>Clin. Immunol. Immunopathol.</u> 60:471-483 (1991)	
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 Application Number 08/781,296
 Filing Date January 13, 1997
 First Named Inventor John B. Harley et al.
 Group Art Unit Not yet assigned
 Examiner Name Not yet assigned
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Sheet 7

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Application Number	08/781,296
Filing Date	January 13, 1997
First Named Inventor	John B. Harley et al.
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	OMRF 161

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		Fox, et al., "Detection of Epstein-Barr Virus-Associated Antigens and DNA in Salivary Gland Biopsies from Patients with Sjogren's Syndrome", <u>J. Immunol.</u> , 137:3162-3168 (1986)	
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		Harley & Gaither, "Autoantibodies" <u>Rheum. Dis. Clin. N. Amer.</u> , 14:43-56 (1992)	
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		Harley & James, "Review Articles: Autoepitopes in Lupus", <u>J. Lab. Clin Med.</u> , 126(6):509-516 (1995)	
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		Herbert, et al., <u>Dictionary of Immunology</u> 3 rd Ed. Blackwell Scientific Publications Oxford UK page 14 91985)	
		Heslop, et al., "Long-Term Restoration of Immunity Against Epstein-Barr Virus Infection by Adoptive Transfer of Gene-Modified Virus-Specific T Lymphocytes", <u>Nature Med.</u> , 2:551-555 (1996)	

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Attorney Docket Number	OMRF 161

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		Hinterberger, "Isolation of Small Nuclear Ribonucleoproteins Containing U1, U2, U4, U5, and U6 RNAs", <u>Biol. Chem.</u> , 258:2604-2613 (1983)	
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		James, et al., "Inbred Mice Strains Differ in Their Capacity to Develop Spliceosomal Autoimmunity After Peptide Immunization", <u>Arthritis Rheum.</u> , 38:S226 (1995)	

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		James & Harley, "Linear Epitope Mapping of an Sm B/B' Polypeptide", <u>J. Immunol.</u> , 148:2074-2079 (1992)	
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Sheet 11 of 21

Application Number 08/781,296
 Filing Date January 13, 1997
 First Named Inventor John B. Harley et al.
 Group Art Unit Not yet assigned
 Examiner Name Not yet assigned
 Attorney Docket Number OMRF 161

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

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		Lehman, et al., "Spreading of T-Cell Autoimmunity to Cryptic Determinants of an Autoantigen," <u>Nature</u> 356:155-157 (1992)	
		Lerner, et al., "Are snRNPs Involved in Splicing?" <u>Nature</u> 283:220-224 (1980)	

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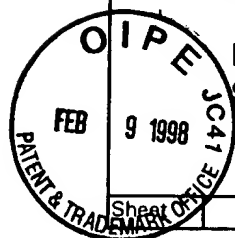
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	08/781,296
Filing Date	January 13, 1997
First Named Inventor	John B. Harley et al.
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	OMRF 161

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		Newkirk, et al., "Detection of Cytomegalovirus, Epstein-Barr Virus and Herpes Virus-6 in Patients with Rheumatoid Arthritis With or Without Sjogren's Syndrome", <u>Br. J. Rheum.</u> , 33:317-322 (1994)	
		Nider, et al., <u>PNAS</u> 87:9933 (1990)	
		Ohsone, et al., "Molecular Cloning of cDNA Encoding Sm Autoantigen: De.ivation of a cDNA for a B Polypeptide of the U Series of Small Nuclear Ribonucleoprotein Particles," <u>Proc. Natl. Acad. Sci. USA</u> 86:4249-4253 (1989)	
		Palfi, et al, "Purification of the Major UsnRNPs from Broad Bean Nuclear Extracts and Characterization of their Protein Constituents," <u>Nucleic Acids Res.</u> 17:1445-1458 (1989)	
		Petersen, et al, "Altered Immune Response to Glycine-Rich Sequences of Epstein-Barr Nuclear Antigen-1 in Patien's with Rheumatoid Arthritis and Systemic Lupus Erythematosus", <u>Arthritis Rheum.</u> , 33: 993-1000 (1990)	
		Petterson, et al., "The Structure of Mammalian Small Nuclear Ribonuceoproteins", <u>J. Biol. Chem.</u> , 259:5907-5914 (1984)	
		Pflugfelder, et al., "Epstien-Barr Virus and the Lacrimal Gland Pathology of Sjogren's Syndrome", <u>Am. J. Pathol.</u> , 143:49-64 (1993)	
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		Phillips & Christian, "Myxovirus Antibody Increases in Human Connective Tissue Disease", <u>Science</u> , 168:982-4 (1970)	
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		Query, et al., "A Common RNA Recognition Motif Identified within a Defined U1 RNA Binding of the 70K U1 snRNP Protein," <u>Cell</u> 57:89-101 (1989)	

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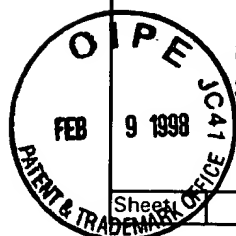
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		Ravirajan & Staines, "Involvement in Lupus Disease of Idiotypes Id.F-423 and Id.IV-228 Defined, Respectively, Upon Foetal and Adult MRL/Mp-lpr/lpr DNA-binding Monoclonal Autoantibodies" <u>Immunology</u> , 74:342-347 (1991)	
		Reichlin, et al., "Autoantibodies to the URNP Particles: Relationship to Clinical Diagnosis and Nephritis," <u>Clin. Exp. Immunol.</u> 83:286-290 (1991)	
		Reichlin, et al., "Concentration of Autoantibodies to native 60-kd Ro/SS-A and Denatured 52-kd Ro/SS-A in Eluates from the Heart of a Child Who Died with Congenital Complete Heart Block," <u>Arth. And Rheum.</u> 37:1698-1703 (1994)	
		Renz, M., et al, "Expression of the Major Human Ribonucleoprotein (RNP) Autoantigens in <i>Escherichia coli</i> and their Use in an EIA for Screening Sera from Patients with Autoimmune Diseases," <u>Clin. Chem.</u> 35:1861-1863 (1989)	
		Reuter, et al., <u>PNAS</u> 83:8689-8693 (1986)	
		Rhodes, et al., "Autoantibodies in Infectious Mononucleosis Have Specificity for the Glycine-Alanine Repeating Region of the Epstein-Barr Virus Nuclear Antigen", <u>J. Exp. Med.</u> 165:1026-1040 (1987)	
		Rokeach, et al., "Molecular Cloning of a cDNA Encoding the Human Sm-D Autoantigen," <u>Proc. Natl. Acad. Sci. USA</u> 85:4832-36 (1988)	
		Rokeach, et al., "Primary Structure of a Human Small Nuclear Ribonucleoprotein Polypeptide as Deduced by cDNA Analysis", <u>J. Biol. Chem.</u> , 264:5024-30 (1989)	
		Rose, et al., "T-Cell Regulation in Autoimmune Thyroiditis," <u>Immunol. Reviews</u> 55:229-314 (1981)	
		Rose, et al., "Genetic Regulation in Autoimmune Thyroiditis," Talal N. ed. Autoimmunology <u>Genetic Immunologic Virologic, and Clinical Aspects</u> . New York: Academic Press, 63-87 (1977)	
		Rose, et al., "Studies on Experimental Thyroiditis," <u>Ann. NY Acad. Sci.</u> 124:201-108 (1965)	

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		Sabbatini, et al., "Autoantibodies from Patients with Systemic Lupus Erythematosus Bind a Shared Sequence of AmD and Epstein-Barr Virus-Encoded Nuclear Antigen EBNA 1", <u>Eur. J. Immunol.</u> , 23:1146-1152 (1993)	
		Saito, et al., "Detection of Epstein-Barr Virus DNA by Polymerase Chain Reaction in Blood and Tissue Biopsies from Patients with Neocarcinostatin", <u>The Journal of Immunology</u> , 142(4):1159-1165 (1989)	
		Schaack, "Molecular Mimicry in HLA-B-27-Related Arthritis," <u>Annals of Internal Medicine</u> , 111(7):581-591 (October 1, 1989)	
		Schmauss, et al., "A Comparison of snRNP-Associated Sm-Autoantigens: Human N, Rat N and Human B/B (abstract)", <u>Nuc. Acid Res.</u> , 17:1733-43 (1989)	
		Schoenfeld, et al, "Modulation of Experimental SLE Induced in Naive Mice by a Pathogenic Anti-DNA Idiotypic (16/6 Id)," <u>Proceedings of the Second International Conference on Systemic Lupus Erythematosus</u> Tokyo, Japan Professional Postgraduate Services 83 (1989)	
		Schoenfeld, et al, "Pathogenic Idiotypes of Autoantibodies in Autoimmunity: Lessons from New Experimental Models of SLE," <u>FASEB J.</u> 4:2646-2651 (1990)	
		Scofield, et al., "60kD Ro/SSA Autoepitopes are Found in Regions of Homology Between Ro/SSA and the Nucleocapsid Protein of Vesicular Stomatitis Virus," <u>Arthritis and Rheumatism</u> , 33(9):S101 (1990)	
		Scofield, et al., "Autoantigenicity of Ro/SSA Antigen is Related to a Nucleocapsid Protein of Vesicular Stomatitis Virus", <u>Proc. Natl. Acad. Sci. USA</u> , 88:3343-3347 (1991)	
		Scofield, R., "A Common Autoepitope Near the carboxyl Terminus of the 60-kD Ro Ribonucleoprotein: Sequence Similarity with a Viral Protein," <u>Journal of Clinical Immunology</u> 11(6):378-388 (1991)	
		Scofield, et al., "The Autoantigenicity of Human 60kD Ro/SSA is Related to Homologies Between Ro/SSA and the Nucleocapsid Protein of Vesicular Stomatitis Virus," <u>Clinical Research</u> , 38(2):316A, (1990)	
		Scofield, et al., "Development of the Anti-Ro Autoantibody Response in a Patient with Systemic Lupus Erythematosus", <u>Arthritis & Rheumatism</u> , 39(10):1664-1688 (1996)	

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		Scofield, et al., "Immunization with Short Peptides from the Sequence of the Systemic Lupus Erythematosus-Associated 60-kDa Ro Autoantigen Results in Anti-Ro Ribonucleoprotein Autoimmunity", <u>J. Immunology</u> , 4059-4066 (1996)	
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		Sillikens, P., et al, "cDNA Cloning of the Human U1 snRNA-Associated A Protein: Extensive Homology Between U1 and U2 snRNP-Specific Proteins," <u>EMBO Journal</u> 6:3841-3848 (1987)	
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		Sturgess, A., et al., "Characteristics and Epitope Mapping of a Cloned Human Autoantigen La," <u>J. Immun.</u> 3212-3218 (1988)	
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		Suzuki, et al., "Viral Interleukin 10 (IL-10), the Human Herpes Virus 4 Cellular IL-10 Homologue, Induces Local Anergy to Allogeneic and Syngeneic Tumors", <u>J. Exp. Med.</u> , 182:477-486 (1995)	
		Takeda, Y., et al., "Antigenic Domains on the U1 Small Nuclear Ribonucleoprotein-associated 70kD Polypeptide; a comparison of regions selectively recognized by Human and Mouse Autoantibodies and by Monoclonal Antibodies," Chem. Abstracts 116(1): ab. No. 4803a (January 6, 1992)	
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		Theissen, et al., "Cloning of the Human cDNA for the U1 RNA-associated 70K Protein," <u>EMBO J.</u> 5:3209-17 (1986)	
		Tigbe, Production of Human Rheumatoid Factors (RF) by SCID Mice Transplanted with Synovial Membrane Lymphocytes, presented at the Arthritis Foundation Fellows Conference, Amelia Island, Plantation, Florida, December 8-10 (1989)	
		Tincani, et al., "Induction of Experimental SLE in Naive Mice by Immunization with Human Polyclonal anti-DNA Antibody Carrying the 16/6 Idiotype," <u>Clinical and Exp. Rheum.</u> 11:129-134 (1993)	
		Toda, et al., Sjogren's syndrome (SS) and Epstein-Barr virus (EBV) reactivation. In Lacrima Gland, Tear Film, and Dry Eye Syndrome D.A. Sullivan, ed. pp 647-650 (Plenum Press, New York 1994)	
		Tsai, et al., "Detection of Epstein-Barr Virus and Cytomegalovirus Genome in White Blood Cells from Patients with Juvenile Rheumatoid Arthritis and Childhood Systemic Lupus Erythematosus", <u>Int. Arch. Allergy Immunol.</u> , 106:235-240 (1995)	
		Tsuzuka, et al., "Lupus Autoantibodies to Double-stranded DNA Cross-react with Ribosomal Protein S1", <u>Arthritis & Rheumatism</u> , 38(9):abstract 726 (1995)	

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		Tzartos, et al., Autoimmunity 8:259-270 (1991)	
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		Wagstaff, et al., <u>Drugs</u> , 47:153-205 (1994)	
		Waltuck and Buyon, "autoantibody-associated Congenital Heart Block: Outcome in Mothers and Children," <u>Ann. Intern. Med.</u> 120:544-551 (1994)	
		Warner & Carp, "Multiple Sclerosis Etiology - an Epstein-Barr Virus Hypothesis", <u>Med. Hypotheses</u> , 25:93-97 (1988)	

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		Watson, et al., "Certain Properties Make Substances Antigenic," in Molecular Biology of the Gene, Fourth Edition, page 836, paragraph 3, (The Benjamin/Cummings Publishing Company, Menlo Park, 1987)	
		Whittingham, et al., "Epstein-Barr Virus as an Etiological Agent in Primary Sjogren's Syndrome", <u>Med Hypothesis</u> , 22:373-386 (1987)	
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Examiner's Signature		Date Considered	
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Complete if Known

Application Number	08/781,296
Filing Date	January 13, 1997
First Named Inventor	John B. Harley et al.
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	OMRF 161

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

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